

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK

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IN RE NAMENDA DIRECT PURCHASER  
ANTITRUST LITIGATION

Case No. 1:15-cv-07488-CM (RWL)

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**FOREST'S OPPOSITION TO PLAINTIFFS' MOTION *IN LIMINE* NO. 7:  
PRECLUDE IMPROPER JUSTIFICATIONS FOR THE LEXAPRO AMENDMENT**

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There is overwhelming evidence that by agreeing to the Lexapro Amendment, Mylan permitted Forest to recognize tens of millions of dollars of value in decreased Medicaid rebates. This evidence will show that there was no actionable reverse payment here — as Forest received a significant net benefit from the settlement, rather than making the large sacrifice of its monopoly profits as *FTC v. Actavis, Inc.* requires. Unless, that is, DPPs succeed in rewriting *Actavis* to ignore the brand's perspective and focus solely on whether the agreement induced the generic to settle. That is what their argument about jury instructions — styled as Motion *In Limine* No. 7 (“DPPs’ MIL 7”) — seeks to do. But the Supreme Court in *Actavis*, circuit and district courts interpreting *Actavis*, the Federal Trade Commission interpreting *Actavis*, academics writing both before and after *Actavis*, and even DPPs’ own proffered expert all agree that a reverse payment must be **both** a large sacrifice of monopoly profits by the patentee **and** a large, unexplained benefit to the generic in order to raise antitrust concerns. See, e.g., *FTC v. Actavis, Inc.*, 570 U.S. 136, 156–58 (2013); *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 405 (3d Cir. 2015) [hereinafter “*Lamictal*”]; *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 252–53 (3d Cir. 2017); *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 332 (D.R.I. 2017); *In re Impax Labs., Inc.*, 2019 FTC LEXIS 25, at \*56 (F.T.C. Mar. 28, 2019); Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, & Carl Shapiro, *Activating Actavis*, 28 ANTITRUST 16, 18 (2013); Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, & Carl Shapiro, *The Actavis Inference: Theory and Practice*, 67 RUTGERS L. REV. 585, 594 (2015); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 408 (2003); Ex. 1, Nov. 10, 2017 Dep. of Einer Elhauge (“Elhauge (Nov. 10) Dep.”) 265:15–18 (Q. “In your model you look at the payment from Forest’s perspective and from Mylan’s perspective. Correct, sir?” A. “Correct.”).

The question of whether there was a profit sacrifice is just another way of asking whether the patentee obtained unexplained value from the agreement, from its own perspective. If the patentee did not sacrifice its monopoly profits because the reverse payment is “explained” by the value the patentee received from benefits unrelated to generic delay, there is no inference that the patent is weak and that the patentee had to pay to maintain its monopoly. *Actavis*, 570 U.S. at 156 (“Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.”).

Moreover, DPPs’ argument makes no sense in light of the fact that a payment less than avoided litigation costs is permissible under *Actavis* — a legal proposition that is undisputed between the parties. ECF No. 699-1, Revised Pls.’ Contentions at ¶ 218 (arguing that DPPs’ have shown Forest’s payment to Mylan was large because it allegedly exceeded Forest’s saved litigation costs); ECF No. 699-2, Defs.’ Contentions (“Forest’s Cont.”) at 3 (arguing that payment to Mylan under patent settlement agreement was below Forest’s avoided litigation costs, and thus there was no large reverse payment); *see also Actavis*, 570 U.S. at 156, 159. The reason that a payment smaller than avoided litigation costs is not actionable is that it simply is not a large sacrifice by the patentee — the patentee is taking money that it would have paid its lawyers, experts, etc., and instead using that same money to reach a settlement. *Actavis*, 570 U.S. at 156. Just like the Medicaid savings that DPPs contest here, Forest’s saved litigation costs are not compensation to Mylan for services “that Mylan performed” and do not represent value that Mylan received. DPPs’ MIL 7 at 2. Thus, DPPs’ argument is valid only if *Actavis* is rewritten to eliminate the Supreme Court’s instruction that a payment smaller than saved litigation costs is legal.

Accordingly, DPPs' motion seeking to withhold from the jury evidence of the Medicaid savings Forest expected to achieve from the Lexapro Amendment should be denied.

### **FACTUAL BACKGROUND**

The amendment to Forest and Mylan's distribution and supply agreement for authorized generic Lexapro created value for both parties. ECF No. 616, Defs.' Statement of Undisputed Material Facts in Support of Defs.' Mot. for Summ. J. ("Forest's SOF") at ¶¶ 265–266. Forest prepared several forecasts, each of which estimated that Forest would save more than \$20 million in Medicaid rebate savings alone (on top of additional savings not at issue in DPPs' motion) by shifting the responsibility to manufacture authorized generic Lexapro from Forest to Mylan. Forest's Cont. at 4–5; Forest's SOF at ¶ 265. While Mylan's agreement to relieve Forest of its contractual obligation to manufacture authorized generic Lexapro was the only realistic way that Forest could have achieved those significant projected savings, the savings did not come directly from Mylan. See Forest's SOF ¶¶ 218–235, 257, 265. DPPs thus contend that Forest's savings should not count under *Actavis* because, although Mylan created the savings for Forest, the savings to Forest were not in the form of a direct payment from Mylan to Forest. DPPs' MIL 7 at 2.

But these savings are directly relevant to key issues in the case — namely, whether any payment was "explained" and thus whether Forest made a "large" reverse payment (*i.e.*, a large sacrifice of its monopoly profits). *Actavis*, 570 U.S. at 156–158. As such, Forest's Medicaid savings should not be shielded from the jury.

### **ARGUMENT**

Because DPPs are trying to use the *in limine* process to improperly argue jury instructions, Forest here seeks to make clear the myriad reasons why DPPs are wrong.

## I. The Value Forest Received Under Its Settlement Must Be Considered Under *Actavis*

*Actavis* requires that reverse payment settlements be valued from the perspective of *both* the brand *and* the generic. DPPs have cherry-picked references to half of the legal test discussing the generic’s perspective to suggest that the Court should preclude evidence of the value that Forest expected to receive. DPPs’ MIL 7 at 1. In reality, however, *Actavis* is rife with recognition that value to the brand is critical to the analysis of a reverse payment settlement agreement. *Actavis*, 570 U.S. at 156 (recognizing that payment may be in exchange for service that provides value to the brand, like “distributing the patented item or helping to develop a market for that item”), 159 (considering whether alleged reverse payment reflects the “payor’s anticipated future litigation costs” and recognizing “any other convincing justification”).

### A. **Courts, the FTC, Academics, and DPPs’ Expert All Agree That a Reverse Payment Must Be Considered from the Perspective of Both Parties**

DPPs’ argument that “*Actavis* looks to the value conferred by the brand (Forest) upon the generic (Mylan)” (DPPs’ MIL 7 at 1 (emphasis omitted)) *only* and that value conferred to *Forest* is irrelevant is belied by the case law DPPs rely upon. *See id.* (citing *Loestrin*, 261 F. Supp. 3d at 332 (“The text of *Actavis* suggests that the Court should consider [the value to] both [the brand and generic] in considering an alleged unlawful reverse payment.”)). Indeed, circuit and district courts, and even the FTC, recognize that *Actavis* requires an analysis of whether a brand is simply sacrificing its monopoly profits or instead paying to receive something of value. *See Lamictal*, 791 F.3d at 405 (asking whether “the source of the benefit to the claimed infringer is something costly to the patentee”); *Lipitor*, 868 F.3d at 252–53 (reverse payment allegations sufficient because they described a sacrifice of profits by patentee and a benefit for generic); *Impax Labs.*, 2019 FTC LEXIS 25, at \*56 (considering the alleged payment from both parties’ perspective, including considering the “revenues [the patentee] forgone” by virtue of making the payment).

Antitrust scholars likewise agree that the value of reverse payment settlements must be evaluated from the perspective of the brand to determine whether anticompetitive effects are present. In an article cited favorably by DPPs, the authors conclude: “Where the [reverse] payment takes a form other than a simple cash transfer from the patentee to the claimed infringer, *consideration should be valued from the perspective of the patentee.*” Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, & Carl Shapiro, *Activating Actavis*, 28 ANTITRUST 16, 18 (2013) (emphasis added); *see also* Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, & Carl Shapiro, *The Actavis Inference: Theory and Practice*, 67 RUTGERS L. REV. 585, 594 (2015) (“for noncash reverse payments, the courts should seek to measure the dollar value sacrificed by the patent holder as a result of the agreement it reached with the alleged infringer”); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 408 (2003) (“If the noncash assets received by the patentholder [in an ancillary agreement] have no well-defined market value, it becomes necessary to estimate their value to the patentholder. If the patentholder is receiving more in value, *as seen through its own eyes*, than it is giving up, the patentholder is making no net payment to the challenger, and there is no basis for presuming that the settlement delays entry in comparison with litigation.”) (emphasis added). That the patentee’s sacrifice must be considered in determining the existence of a reverse payment is therefore not seriously in doubt, and DPPs’ attempts to limit the evidence to exclude considering this side of the analysis is unsupportable. In fact, even DPPs’ proffered reverse payment expert, Einer Elhauge, looked at the payment from both Forest’s and Mylan’s perspective. Ex. 1, Elhauge (Nov. 10) Dep. 265:15–18 (Q. “In your model you look at the payment from Forest’s perspective and from Mylan’s perspective. Correct, sir?” A. “Correct.”).

**B. That *Actavis* Also Mentions Benefits to the Generic Is Unsurprising Because Both Sides Must be Considered**

Nor is it any answer to note that portions of *Actavis* appear directed toward the benefit the generic receives (DPPs' MIL 7 at 1) because *both* a large patentee sacrifice *and* a large and unexplained generic benefit are required for there to be a reverse payment under *Actavis*. In fact, while DPPs emphasize inducement to “the generic challenger” language from *Actavis* (DPPs' MIL 7 at 1), the full quote makes it clear that the payment must also be viewed from the perspective of the patentee. *Actavis*, 570 U.S. at 154 (explaining that a payment may show that “the patentee seeks to induce the generic challenger to abandon its claim *with a share of its monopoly profits* that would otherwise be lost in the competitive market”) (emphasis added). That a generic benefit is required under *Actavis* thus in no way diminishes the need for a patentee sacrifice as well.

**C. *Actavis* is Premised Upon the Theory That There Must Be a Large Patentee Sacrifice in Order to Find an Unlawful Reverse Payment**

*Actavis* repeatedly speaks of the need for a patentee sacrifice to establish an actionable reverse payment. For example, under *Actavis* a reverse payment “amounts to a *purchase* by the patentee of the exclusive right to sell its product.” 570 U.S. at 154 (emphasis added). *Actavis* further held that the “patent, if valid and infringed, might have permitted [the patentee] to charge drug prices sufficient to recoup the reverse settlement payments,” but obviously to “recoup” there must first be a loss. *Id.* at 147. And *Actavis* noted that an unlawful reverse payment settlement “simply keeps prices at patentee-set levels, potentially producing the full patent-related \$500 million monopoly return while dividing that return between the challenged patentee and the patent challenger” — thus requiring profit sacrifice (*i.e.*, the division of the profits between the brand and the generic). *Id.* at 154.

In addition, as the following sections demonstrate, many other aspects of the *Actavis* ruling demonstrate that an antitrust challenge to a reverse payment requires a large, unexplained profit sacrifice from the brand's perspective.

### **1. Saved Litigation Costs Are Not Reverse Payments Because They Are Not Sacrifices By the Patentee**

As DPPs concede, *Actavis* held that a payment representing nothing more than the patentee's saved litigation costs would not raise antitrust concerns, as it would not "bring[] about anticompetitive effects." *Actavis*, 570 U.S. at 159. The reason for this is simple: where a patentee pays the generic challenger what it would otherwise spend on litigation, it has made no profit sacrifice. A patentee who would have paid its lawyers \$10 million, and instead pays its adversary \$10 million, has lost nothing; only its lawyers lose out. Thus, focusing on the patentee's sacrifice explains this aspect of *Actavis*. See, e.g., *Impax Labs.*, 2019 FTC LEXIS 25, at \*56 n.19 ("[I]t is the excess of Endo's payment over its other savings or justified benefits that should be understood as directed toward buying market exclusivity.").

### **2. A Reverse Payment Is Unusual Only Because of the Patentee's Sacrifice**

*Actavis* held that a reverse payment is suspect because it is "unusual" and "quite different" from a traditional, commonplace compromise. *Actavis*, 570 U.S. at 147, 152. But what makes a reverse payment "unusual?" It cannot be that the generic benefits from the settlement, as most settlements provide both parties with greater value than they expect to receive from litigating. See, e.g., *In re Joint E. & S. Dist. Asbestos Litig.*, 14 F.3d 726, 729 (2d Cir. 1993) (stated purpose of class certification is to "facilitate the formation of a settlement that will mutually benefit both [parties]"); *United States v. De La Mata*, 535 F.3d 1267, 1270 (11th Cir. 2008) (settlement of forfeiture claim mutually-beneficial, including because of saved litigation costs); *Judkins v. HT Window Fashion Corp.*, 529 F.3d 1334, 1340 (Fed. Cir. 2008) ("The fact that both [parties] took

from the settlement something of value points to a constructive, mutually beneficial resolution to a legitimate dispute.”). And consideration paid in *every settlement* “induce[s]” (DPPs’ MIL 7 at 1) the recipient to settle. Instead, it is the patentee’s willingness to make a large and unexplained short-term sacrifice that makes a reverse payment settlement unusual. *See, e.g., In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 262 (D. Mass. 2014) (“[a] large payment would be an irrational act unless the patentee believed that generic production would cut into its profits”) (quoting Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court’s Actavis Decision*, 15 MINN. J.L. SCI. & TECH. 3, 25 (2014)). A sacrifice is thus required.

### **3. The Inference of Potential Patent Weakness on Which *Actavis* Relies Requires a Large Sacrifice by the Patentee**

*Actavis* held that an “unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival,” and could be a “workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.” 570 U.S. at 157–58; *see also id.* at 154–55 (reverse payment “signal[s] to other potential challengers that the patentee lacks confidence in its patent”). This “surrogate” necessarily requires a large patentee sacrifice because only the patentee’s perspective is relevant to whether the “patentee ha[d] serious doubts about the patent’s survival.” *Id.* at 157–58. Put another way, *Actavis* assumes that a large, unexplained reverse payment is something that would be irrational for the patentee unless it was worried that otherwise the patent litigation would reveal the patent to be weak — but a settlement that involves no large sacrifice simply does not lead to such an inference.

Evidence of the value Forest received is crucial to demonstrate that, in fact, the purpose of Forest’s payment to Mylan was to obtain these benefits and not to delay entry. For example, if Forest’s expected Medicaid savings and value from the second year of profit share revenues are

credited (as they should be), Forest received more than it gave up through the Lexapro Amendment. Thus, there can be no inference that Forest was concerned about patent weakness. *Id.* at 157 (“An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival.”).

#### **4. The Inference of Market Power on Which *Actavis* Relies Similarly Assumes the Existence of a Large Patentee Sacrifice**

*Actavis* held that “where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the [market] power to bring that harm about in practice.” *Actavis*, 570 U.S. at 157. If such a payment were viewed from the perspective of the generic’s benefit, this inference would be a *non sequitur*, as the generic’s receipt of value is a poor indicator of whether the *patentee* has market power. Indeed, *Actavis* explicitly assumes that a reverse payment is something that the patentee will “recoup” — which must by definition mean a sacrifice by the patentee. *See id.* at 147 (“[Company’s] patent, if valid and infringed, might have permitted [the patentee] to charge drug prices sufficient to recoup the reverse settlement payments”); *see also Brooke Grp. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993) (requiring similar sacrifice and recoupment in predatory pricing context). Thus, *Actavis* depends on the existence of a large sacrifice by the patentee in order to provide any basis to infer the market power that the Court suggests.

#### **II. “Cognizable Value” to Forest Is Not Limited to Value Flowing From Mylan as DPPs Contend Because *Actavis* Never Suggested Any Such Limitation**

DPPs also argue that because Forest’s Medicaid savings resulted from Forest having lower rebate obligations to the government due to the Lexapro Amendment — and not because it received a benefit directly from Mylan — the savings cannot be considered as an explanation for Forest’s payment to Mylan. DPPs’ MIL 7 at 2. This argument misinterprets *Actavis* to hold that the only cognizable justification for a payment is compensation for services performed by the

generic, presumably based on the fact that the Supreme Court mentioned “fair value for services” as one reason that there might not be such a sacrifice. *Id.* (citing *Actavis*, 570 U.S. at 156). But the Supreme Court recognized that compensation for services is merely one of multiple potential explanations for an alleged reverse payment. *Actavis*, 570 U.S. at 156 (finding that a payment from the patentee to the alleged infringer “*may* reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item. ***There may be other justifications.***”) (emphasis added).

Contrary to DPPs’ contention, nothing in *Actavis* suggests that evidence of Forest’s expected Medicaid rebate savings should be excluded simply because the savings did not come from Mylan’s pocket. It is undisputed that it is appropriate to consider saved litigation costs that a patentee realizes by paying less money to its lawyers (as opposed to the generic challenger). *See supra* § I.C.1. DPPs’ argument that the Medicaid savings Forest realized by entering the Lexapro Amendment should not count because they did not come out of Mylan’s pocket (DPPs’ MIL 7 at 2) would similarly require evidence of Forest’s saved litigation costs to be excluded, in contravention of *Actavis*. *See* 570 U.S. at 156.

Further, *Actavis* simply does not set forth an exhaustive list of justifications that a patentee may offer to explain its payment to an alleged infringer. *Id.* at 158 (reasoning that “in the absence of some other justification” the antitrust laws are likely to forbid an arrangement that seeks to maintain and to share patent-generated monopoly profits), 159 (indicating that the likelihood of a reverse payment bringing about anticompetitive effects depends upon several factors “and the lack of any other convincing justification”). Indeed, even the FTC in *Actavis* understood that the relevant question was whether there was a “business justification” — not narrowly whether there was compensation for services rendered by the generic. *See* Reply Brief for Petitioner at 24, *FTC*

v. Actavis, Inc., 570 U.S. 136 (2013) (“In defending against antitrust challenges, however, manufacturers should have ready access to whatever evidence supplied a *business justification* for their multi-million dollar transactions.”) (emphasis added). DPPs therefore cannot prevent the jury from considering the evidence of Forest’s substantial Medicaid savings.

### **CONCLUSION**

For the foregoing reasons, Forest respectfully requests that the Court deny DPPs’ Motion  
*In Limine* No. 7: Preclude Improper Justifications for the Lexapro Amendment.

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Respectfully submitted,

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